

90-DAY RESPONSE

DCI Number: GDCI-122101-1705

Data Call-In Information

Company Name	ARCH TREATMENT TECHNOLOGIES, INC.
Company Address	360 INTERSTATE NORTH PARKWAY, SUITE 450 ATLANTA, GA 30339
DCI Type	Generic
Issued Date	04/12/2017
90-Day Response Deadline	07/21/2017
CRM Information	Walsh, Linsey
Chemical Name	Propiconazole
Chemical Number	122101

90-Day Response Information

Tracking Number	CDX_DCI_2017_000581
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DCI Level Documents

File Name	File Type	MRID	CBI	Submitted Date
75506_cvr litr_90day_07JULY2 017.pdf	Submission Cover Letter	N.A.	N	07/07/2017

EPA Product Registration Number(s)

75506-3	I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.
Source EPA Registration Number(s)	
75506-9	I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.
Source EPA Registration Number(s)	
75506-7	I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.
Source EPA Registration Number(s)	
75506-14	I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.

Product ingredient source information may be entitled to confidential treatment

Source EPA Reg strat on Number(s)	
75506-10	I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.
Source EPA Reg strat on Number(s)	
75506-12	I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.
Source EPA Reg strat on Number(s)	
75506-21	I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.
Source EPA Reg strat on Number(s)	
Guideline Requirement Number(s)	
Guideline Requirement Number - 835.1110	
Study T t e	Activated sludge sorption isotherm
Protoco	N
Target Subm ss on Date	04/12/2018
Use Pattern	A; C; BB; X
Test Substance	TGAI
T me Frame	12 month(s)
Footnote(s)	15. These data are required for antimicrobial use sites. 30. EPA has a published final guideline for this study: http://www.regulations.gov#!documentDetail;D=EPA-HQ-OPPT-2009-0152-0003 .
Reg strant Response	N.A.
Guideline Requirement Number - 835.3110	
Study T t e	Ready biodegradability
Protoco	N
Target Subm ss on Date	04/12/2018
Use Pattern	A; C; BB; X
Test Substance	TGAI
T me Frame	12 month(s)

Footnote(s)	<p>15. These data are required for antimicrobial use sites.</p> <p>29. EPA has a published final guideline for this study: http://www.regulations.gov#!documentDetail;D=EPA-HQ-OPPT-2009-0152-0017 . The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test</p>
Reg strant Response	N.A.
Guideline Requirement Number - 835.3220	
Study T t e	Porous pot test
Protoco	N
Target Subm ss on Date	04/12/2018
Use Pattern	A; C; BB; X
Test Substance	TGAI
T me Frame	12 month(s)
Footnote(s)	<p>15. These data are required for antimicrobial use sites.</p> <p>28. EPA has a published final guideline for this study: http://www.regulations.gov#!documentDetail;D=EPA-HQ-OPPT-2009-0152-0024 . The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.</p>
Reg strant Response	N.A.
Guideline Requirement Number - 835.3240	
Study T t e	Simulation Test-Aerobic Sewage Treatment-Activated Sludge
Protoco	N
Target Subm ss on Date	04/12/2018
Use Pattern	A; C; BB; X
Test Substance	TGAI
T me Frame	12 month(s)
Footnote(s)	<p>15. These data are required for antimicrobial use sites.</p> <p>27. EPA has a published final guideline for this study: http://www.regulations.gov#!documentDetail;D=EPA-HQ-OPPT-2009-0152-0034 . The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.</p>
Reg strant Response	N.A.
Guideline Requirement Number - 835.3280	
Study T t e	Simulation Tests to Assess the Biodegradability of Chemicals
Protoco	N

Target Submission Date	04/12/2018
Use Pattern	A; C; BB; X
Test Substance	TGAI
Time Frame	12 month(s)
Footnote(s)	15. These data are required for antimicrobial use sites. 26. EPA has a published final guideline for this study: http://www.regulations.gov#!documentDetail;D=EPA-HQ-OPPT-2009-0152-0036 . The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.
Regulant Response	N.A.

Guideline Requirement Number - 850.1075

Study Title	Fish acute toxicity test, freshwater and marine
Protocol	N
Target Submission Date	04/12/2018
Use Pattern	A; C; BB; X
Test Substance	TGAI
Time Frame	12 month(s)
Footnote(s)	14. These data are required for conventional use sites. 23. For freshwater species, study must be conducted with fathead minnow. 33. 850.1400, saltwater fish early life stage study may be waived if an acceptable 850.1075, freshwater fish acute toxicity study with a fathead minnow is submitted. In lieu of a saltwater fish early life stage study (850.1400), an acute to chronic ratio (ACR) will be calculated using data from an acceptable freshwater fish acute toxicity study (850.1075 with a fathead minnow).
Regulant Response	N.A.

Guideline Requirement Number - 850.1400

Study Title	Fish early-life stage toxicity test
Protocol	N
Target Submission Date	04/12/2018
Use Pattern	A; C; BB; X
Test Substance	TGAI
Time Frame	12 month(s)

Footnote(s)	<p>14. These data are required for conventional use sites.</p> <p>16. Study must be conducted using saltwater fish species.</p> <p>33. 850.1400, saltwater fish early life stage study may be waived if an acceptable 850.1075, freshwater fish acute toxicity study with a fathead minnow is submitted. In lieu of a saltwater fish early life stage study (850.1400), an acute to chronic ratio (ACR) will be calculated using data from an acceptable freshwater fish acute toxicity study (850.1075 with a fathead minnow).</p>
Reg strant Response	N.A.
Guideline Requirement Number - 850.2100	
Study T t e	Avian acute oral toxicity test
Protoco	N
Target Subm ss on Date	04/12/2018
Use Pattern	A; C; BB; X
Test Substance	TGAI
T me Frame	12 month(s)
Footnote(s)	<p>14. These data are required for conventional use sites.</p> <p>18. Study must be conducted using a passerine species. The OCSPP 850.2100 guideline currently recommends the submission of a protocol for EPA review prior to initiation of tests conducted with passerine species. Data submitters are encouraged to consider the recommendations contained in relevant EPA reference documents (i.e., OCSPP 850.2100, EFED Guidance for Reviewing OCSPP 850.2100 Avian Oral Toxicity Studies Conducted with Passerine Birds, EFED Guidance for Use when Regurgitation is Observed in Avian Acute Toxicity Studies with Passerine Species) when preparing test protocols. A protocol does not need to be submitted to EPA for review prior to test initiation if it reflects these recommendations. If a data submitter elects to submit a protocol to EPA, in order to facilitate the review process, any aspects of a proposed study design that differ from this guidance should be noted and accompanied by a descriptive rationale which addresses why they are not expected to adversely impact the quality of the resulting study.</p>
Reg strant Response	N.A.
Guideline Requirement Number - 850.2300	
Study T t e	Avian reproduction test
Protoco	N
Target Subm ss on Date	04/12/2019
Use Pattern	A; C; BB; X
Test Substance	TGAI
T me Frame	24 month(s)
Footnote(s)	<p>14. These data are required for conventional use sites.</p> <p>17. Study must be conducted using mallard duck.</p>

Reg strant Response	N.A.
Guideline Requirement Number - 850.3040	
Study T t e	Field testing for pollinators
Protoco	Y
Target Subm ss on Date	04/12/2019
Use Pattern	A; C; BB; X
Test Substance	TEP
T me Frame	24 month(s)
Footnote(s)	<p>1. USEPA. 2012c. Field Testing for Pollinators. Ecological Effects Test Guidelines OCSPP 850.3040. EPA 712-C-017.</p> <p>3. Tier 3 study. The need for a field test for pollinators will be determined based on the results of lower-tiered tests and/or other lines of data and the need for a refined pollinator risk assessment.</p> <p>14. These data are required for conventional use sites.</p> <p>21. See information and guidance identified in the EPA documents, (i) USEPA. 2012. White Paper in Support of the Proposed Risk Assessment Process for Bees. Submitted to the FIFRA Scientific Advisory Panel for Review and Comment September 11-14, 2012. Office of Chemical Safety and Pollution Prevention Office of Pesticide Programs Environmental Fate and Effects Division, Environmental Protection Agency, Washington DC; Environmental Assessment Directorate, Pest Management Regulatory Agency, Health Canada, Ottawa, CN; California Department of Pesticide Regulation http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2012-0543-0004; (ii) 2014 Guidance for Assessing Pesticide Risks to Bees. Office of Pesticide Programs United States Environmental Protection Agency, Health Canada Pest Management Regulatory Agency, California Department of Pesticide Regulation. June 19, 2014. http://www2.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf.</p> <p>32. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.</p>
Reg strant Response	N.A.
Guideline Requirement Number - 850.3300	
Study T t e	Modified Activated Sludge, Respiration Inhibition Test
Protoco	N
Target Subm ss on Date	04/12/2018
Use Pattern	A; C; BB; X
Test Substance	TGAI
T me Frame	12 month(s)

Footnote(s)	<p>15. These data are required for antimicrobial use sites.</p> <p>25. EPA published draft guidance under guideline 850.6800 and has since published final guidance for this study under guideline 850.3300: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0154-0021. OECD Test Guideline 209 can also be used as guidance for this study, available online at http://www.oecd-ilibrary.org/content/book/9789264070080-en. The results of the Activated Sludge Respiration Inhibition Test (ASRI), GLN 850.3300, will determine which of the four biodegradation tests is/are required. If the ASRI test EC50 is less than or equal to 20 mg/L, then either the (i) Biodegradation in Activated Sludge Study, GLN 835.3280 or (ii) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, GLN 835.3240, or (iii) the Porous Pot Test, GLN 835.3220 is required. If the ASRI test EC50 is greater than 20 mg/L, then the registrant must conduct either: (i) Ready Biodegradability or (ii) a) Biodegradation in Activated Sludge, or b) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, or c) the Porous Pot Test. If the Ready Biodegradability study is conducted and passes, then no further testing is required. If, however, the antimicrobial fails the Ready Biodegradability study, then the (i) Biodegradation in Activated Sludge, or (ii) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, or (iii) the Porous Pot study is required.</p>
Reg strant Response	N.A.
Guideline Requirement Number - 875.1700	
Study T t e	Product Use Information
Protoco	N
Target Subm ss on Date	04/12/2018
Use Pattern	A; C; BB; X
Test Substance	TEP
T me Frame	12 month(s)
Footnote(s)	<p>13. This data requirement is triggered by the antimicrobial paints and stains use sites.</p> <p>15. These data are required for antimicrobial use sites.</p>
Reg strant Response	N.A.
Guideline Requirement Number - 875.2100	
Study T t e	Foliar dislodgeable residue dissipation
Protoco	Y
Target Subm ss on Date	04/12/2019
Use Pattern	A; C; BB; X
Test Substance	TEP
T me Frame	24 month(s)
Footnote(s)	<p>2. Turf grass transferable residue dissipation data are required to assess the residential use of propiconazole on turf.</p> <p>14. These data are required for conventional use sites.</p>

Reg strant Response	N.A.
Guideline Requirement Number - 875.2700	
Study T t e	Product Use Information
Protoco	N
Target Subm ss on Date	04/12/2018
Use Pattern	A; C; BB; X
Test Substance	TEP
T me Frame	12 month(s)
Footnote(s)	<p>12. This data requirement is triggered by the antimicrobial wood preservative use sites.</p> <p>15. These data are required for antimicrobial use sites.</p>
Reg strant Response	N.A.
Guideline Requirement Number - SS-1155	
Study T t e	Residues in Pollen and Nectar/Field Residue Analysis
Protoco	Y
Target Subm ss on Date	04/12/2019
Use Pattern	A; C; BB; X
Test Substance	TEP
T me Frame	24 month(s)
Footnote(s)	<p>4. Tier 2 study. The need for this study will be determined based on the results of lower-tiered studies and/or other lines of data and the need for a refined pollinator risk assessment.</p> <p>14. These data are required for conventional use sites.</p> <p>31. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation. The following elements could be considered when developing study protocol(s) for the monitoring of residues in pollen/nectar. - Consideration of the range of application methods and environmental conditions (e.g., soil and hydric regimes) that the target crop(s) may be under. - Consideration of the attractiveness of the selected crop to pollinators. - Consideration of a collection schedule sufficient to allow for an understanding of the character of residues, in the pollen/nectar and/or plant tissues, over time. - Consideration of data sufficient to determine whether residues of the active ingredient and/or degradation product(s) accumulates in soil and is/are bioavailable for plant to uptake in a following planting, and therefore result in potential exposure to pollinators. - Consideration of the market proportion of the selected target crop(s).</p>
Reg strant Response	N.A.
Guideline Requirement Number - SS-1311	

Study Title	Honey bee adult acute oral toxicity
Protocol	N
Target Submission Date	04/12/2018
Use Pattern	A; C; BB; X
Test Substance	TGAI
Time Frame	12 month(s)
Footnote(s)	6. Tier 1 study. See the OECD 213: OECD Guidelines for the Testing of Chemicals. Honeybees, Acute Oral Toxicity Test. 213. http://www.oecd-ilibrary.org/environment/test-no-213-honeybees-acute-oral-toxicity-test_9789264070165-en 14. These data are required for conventional use sites.
Regulant Response	N.A.

Guideline Requirement Number - SS-1312

Study Title	Honey bee larvae acute oral toxicity
Protocol	N
Target Submission Date	04/12/2018
Use Pattern	A; C; BB; X
Test Substance	TGAI
Time Frame	12 month(s)
Footnote(s)	9. Tier 1 study. OECD Test Guideline 237 may be used to develop a protocol for this study (OECD. 2013 Guidelines for Testing Chemicals. Honey bee (Apis mellifera) larval toxicity test, single exposure.) See: http://www.oecd-ilibrary.org/environment/test-no-237-honey-bee-apis-mellifera-larval-toxicity-test-single-exposure_9789264203723-en 14. These data are required for conventional use sites.
Regulant Response	N.A.

Guideline Requirement Number - SS-1313

Study Title	Honey bee adult chronic oral toxicity
Protocol	Y
Target Submission Date	04/12/2018
Use Pattern	A; C; BB; X
Test Substance	TGAI
Time Frame	12 month(s)

Footnote(s)	<p>7. Tier 1 study. OECD has not yet finalized test guidelines for chronic studies, and efforts are underway to develop standardized guidelines for assessing the effects from chronic exposure to adult and larvae in the laboratory. Discussion of the study design elements for the 10-day adult toxicity test can be found in Appendix O of the European Food Safety Authority (EFSA) guidance document: EFSA. 2013. Guidance on the risk assessment of plant protection products on bees (<i>Apis mellifera</i>, <i>Bombus</i> spp. and solitary bees). EFSA Journal 2013;11(7):3295, 266 pp. doi:10.2903/j.efsa.2013.3295. Available online at: https://www.efsa.europa.eu/en/efsajournal/pub/3295</p> <p>14. These data are required for conventional use sites.</p> <p>32. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.</p>
Reg strant Response	N.A.
Guideline Requirement Number - SS-1314	
Study T t e	Honey bee larvae chronic oral toxicity
Protoco	Y
Target Subm ss on Date	04/12/2018
Use Pattern	A; C; BB; X
Test Substance	TGAI
T me Frame	12 month(s)
Footnote(s)	<p>8. Tier 1 study. OECD has not yet finalized test guidelines for chronic studies with honey bee larvae. OECD Draft Guidance Document Honey Bee (<i>Apis mellifera</i>) Larval Toxicity Test, Repeated Exposure. https://www.oecd.org/env/ehs/testing/Honeybee%20larval%20rep%20expo_REV%20following%20April%202015%20expert%20meeting_Draft%2020%20July%202015.pdf</p> <p>14. These data are required for conventional use sites.</p> <p>32. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.</p>
Reg strant Response	N.A.
Guideline Requirement Number - SS-1319	
Study T t e	Semi-field testing for pollinators (tunnel or colony feeding studies)
Protoco	Y
Target Subm ss on Date	04/12/2019
Use Pattern	A; C; BB; X
Test Substance	TGAI or TEP
T me Frame	24 month(s)

Footnote(s)	<p>5. Tier 2 study. The need for a semi-field test for pollinators (i.e., either a field-feeding test or a tunnel test) will be determined based on the results of lower-tiered tests and/or other lines of evidence, and the need for a refined pollinator risk assessment.</p> <p>14. These data are required for conventional use sites.</p> <p>22. Formal guidelines for semi-field tests do not yet exist; however, information that can help guide the development of either a semi-field tunnel test protocol can be found at OECD 75, see: OECD. 2007. Series on Testing and Assessment Number 75. Guidance document on the honey bee (<i>Apis mellifera</i> L.) brood test under semi-field conditions. Environmental Directorate Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. ENV/JM/MONO(2007)22. 31-Aug-2007. http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)22&doclanguage=en.</p> <p>24. For field-feeding studies see: Oomen et al. 1992: Oomen, P. A. A. DeRuijter and J. Van der Steen. 1992. Method for honey bee brood feeding tests with insect growth-regulating insecticides. <i>Bul OEPP/EPPO Bulletin</i> 22: 613-616.</p> <p>32. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.</p>
Reg strant Response	N.A.
Guideline Requirement Number - SS850.1000	
Study T t e	Chronic Estuarine/Marine Sediment Testing
Protoco	Y
Target Subm ss on Date	04/12/2019
Use Pattern	A; C; BB; X
Test Substance	TGAI
T me Frame	24 month(s)
Footnote(s)	<p>10. This study must be conducted using <i>Leptocheirus plumulosus</i>.</p> <p>15. These data are required for antimicrobial use sites.</p> <p>19. Studies are to be conducted using ORD Study Methods, as specified. The ORD Study Methods can be accessed via EPA's Online Library System. The study methods for <i>Hyallela</i> and <i>Chironomus</i> are available at http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=30003SBA.txt and the study methods for <i>Lepto</i>. are available at http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=30002GRK.txt Registrants must use the test method: "<i>Leptocheirus plumulosus</i>." In: USEPA 2001. "Method for Assessing the Chronic Toxicity of Marine and Estuarine Sediment-associated Contaminants with the Amphipod <i>Leptocheirus plumulosus</i>." Doc. No. EPA 600/R-01/020</p> <p>32. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.</p>
Reg strant Response	N.A.
Guideline Requirement Number - SS850.1000	
Study T t e	Chronic Freshwater Sediment Testing
Protoco	Y
Target Subm ss on Date	04/12/2019

Use Pattern	A; C; BB; X
Test Substance	TGAI
Time Frame	24 month(s)
Footnote(s)	<p>11. This study must be conducted for both <i>Hyalella Azteca</i> and <i>Chironomus dilutes</i>.</p> <p>15. These data are required for antimicrobial use sites.</p> <p>20. Studies are to be conducted using ORD Study Methods, as specified. The ORD Study Methods can be accessed via EPA's Online Library System. The study methods for <i>Hyalella</i> and <i>Chironomus</i> are available at http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=30003SBA.txt and the study methods for <i>Lepto</i>. are available at http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=30002GRK.txt Registrants must use the test method: "Hyalella azteca 42-d Test for Measuring the Effects of Sediment-associated Contaminants on Survival, Growth, and Reproduction." In: USEPA 2000. "Methods for Measuring the Toxicity and Bioaccumulation of Sediment-associated Contaminants with Freshwater Invertebrates." Doc. No. EPA 600/R-99/064.</p> <p>32. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.</p>
Registrant Response	N.A.
Submitter Information	
Submitter	Teri Muchow
Submitted Date	07/07/2017